



UNITED STATES PATENT AND TRADEMARK OFFICE

cl

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,182	10/26/2000	Alfred Von Schuckmann	06275/209001	8134

7590 03/22/2004

William E Booth
Fish & Richardson
225 Franklin Street
Boston, MA 02110-2804

EXAMINER

KOKABI, AZADEH

ART UNIT	PAPER NUMBER
----------	--------------

3743

DATE MAILED: 03/22/2004

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,182

Applicant(s)

VON SCHUCKMANN ET AL.

Examiner

Azy Kokabi

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 28-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 6,520,179 to Von Schuckmann et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 4 of the '179 patent teaches all of the features of the claims 28, 48, 54, and 55.

Some of the specific geometric relationships of the components of the suction tube recited in the dependent claims of the present application are not expressly recited in claim 4 of

Art Unit: 3743

the '179 patent. However, these features are not patentably distinguishable from the device recited in claim 4.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the device recited in claim 4 of the '179 patent because the applicant has not disclosed that the specific geometric relationship recited in the dependent claims provides an advantage, are used for a particular purpose or solves a states problem not solved by the arrangement recited in claim 4. Therefore, the depending claims are not patentably distinguishable from claim 4 of the '179 patent.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 28-48, 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/09085 (the '085 publication).

WO '085 discloses a suction tube including all the features recited in claims 28-47. Generally, the suction tube disclosed includes an elongate body including a feed tube assembly (#14, #18), a plume capture chamber (#30) onto which a mouthpiece is provided. The tip of the feed tube assembly opposite the capture chamber includes an inlet section and inlet. Opposite the inlet is an outlet portion providing the mouthpiece (#32, see figure 1).

An alternative embodiment of the feed tube assembly (#14) is disclosed in figures 7-12C. In the alternate structure, the feed tube assembly (#100), includes an inlet section (#108)

Art Unit: 3743

including an inlet (end of tube 106). As seen in figures 10 and 11A in particular, the inlet section includes a cutting assembly having at least one cutting blade and at least one ram blade (#150).

The cutting blade being one half of the blade structure (#144). The half is made up of opposing triangular sections that taper to a point and define a blade that traverses the inlet (see page 28, lines 27 through page 29, line 2). The ram blade (#150) includes a bearing surface that is suitable for pushing the covering film of a blister into the cavity and widening the cut on the film (see at least figures 12 A-12c). The ram blade (#150) is smaller than the cutting blade and therefore, the cutting blade extends axially forward of the bearing surface of the ram blade (#150). See, e.g., Figures 12A-12C.

With respect to claims 54 and 55, the '085 publication discloses the suction tube in the context of a dry powder inhaler in which the cutting assembly opens a sealed blister containing a powdered medicament (see e.g. Figures 12A-12C and figure 1).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 28-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/40876 (the '876 publication) in view of WO 96/09085 (the '085 publication).

The '876 publication discloses an inhaler that includes all of the features recited in claims 1-54 except for the cutting blade that extends across the inlet.

However, such a cutting blade structure was known at the time of the invention. For example, in the '085 publication, a blister piercing portion is disclosed. The blister-piercing portion includes a cutting assembly (#144) made up of two intersecting blades that extend across an inlet. The blister-piercing portion further includes a ram blade (#150) that is adapted to push the blister cover downward and widen a covering film in order to obtain the medicament (see figures 7-12C).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the suction tube of the inhaler disclosed in the '876 publication to include the blister piercing portion disclosed in the '085 publication. One would have been motivated to do so to provide a more durable blister piercing tip as compared to the unreinforced blade design disclosed by the '085 patent, for example.

Response to Arguments

8. Applicant's arguments filed 12/12/03 have been fully considered but they are not persuasive. Applicant argues that the WO publications fail to disclose a "cutting assembly comprising at least one cutting blade that extends across the inlet, and at least one ram blade wherein the ram blade includes a bearing surface suitable for bearing on the covering film into the cavity of the blister." (See response filed 12/12/036, page 9).

However, the '085 publications does discloses a cutting assembly (140). Page 28 of the '085 publication states that the 140 element includes a pair of crossing internal walls 142 which terminate in a pointed blade structure 144. The WO '085 publication states that "the blade structure 144 leaves four separate flow passages arranged in quadrants within the feed tube 104. The flow passages 146 may optionally stop beyond the attachment point of the blade structure 144 to the inside wall of the host tube. " (see page 28 through page 29). Figure 12A teaches a medicament receptacle being cut by the cutting assembly in order to draw the medicament.

In addition to discloses a cutting blade (#140), the '085 publication discloses a penetrating structure or ram blade (#150). Page 29 of the '085 publication states that the penetrating structure will have a "similar conical blade structure" as the cutting element (#140). The penetrating structure (#150) has a bearing surface on a carrier plate for penetration. The ram structure of the '085 patent is sized to be smaller than the cutting blade and therefore the cutting blade extends axially forward of the bearing surface of the ram blade.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 3743

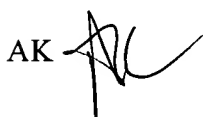
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Azy Kokabi whose telephone number is (703) 306-4154. The examiner can normally be reached on Monday- Friday, 6:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AK



Henry Bennett
Supervisor, Patent Examiner
Group 3700